



## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2012-0549; FRL-9395-5]**

#### **Pyraclostrobin; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of pyraclostrobin in or on multiple commodities which are identified and discussed later in this document. This regulation additionally removes several permanent and time-limited tolerances that will be superseded by tolerances established by this action. Interregional Research Project Number 4 (IR-4) and BASF Corporation requested tolerances associated with pesticide petition (PP) numbers 2E8069 and 2F8038, respectively, under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [*INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0549, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading

Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFNotices@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0549 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0549, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## II. Summary of Petitioned-For Tolerances

In the **Federal Register** of January 16, 2013 (78 FR 3377) (FRL-9375-4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8069) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.582 be amended by establishing tolerances for residues of the fungicide pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its metabolite methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]otolyl] carbamate (BF 500–3), expressed as the parent compound, in or on artichoke, globe at 3.0 parts per million (ppm); endive, belgium at 3.0 ppm; and persimmon at 3.0 ppm. The petition additionally requested that EPA establish tolerances in or on vegetable, bulb, group 3–07 at 0.9 ppm; vegetable, fruiting, group 8–10 at 1.4 ppm; fruit, citrus, group 10–10 at 2.0 ppm; fruit, pome, group 11–10 at 1.5 ppm; oilseed, group 20 at 0.45 ppm;

caneberry subgroup 13–07A at 4.0 ppm; bushberry subgroup 13–07B at 4.0 ppm; small fruit, vine climbing subgroup (except fuzzy kiwi) 13–07F at 2.0 ppm; and low growing berry subgroup 13–07G at 1.2 ppm. Further, upon approval of these subgroup/crop group tolerances the petition also requested that the following existing tolerances be removed for berry, group 13 at 4.0 ppm; fruit, citrus, group 10 at 2.0 ppm; fruit, pome, group 11 at 1.5 ppm; grape at 2.0 ppm; strawberry at 1.2 ppm; vegetable, bulb, group 3 at 0.9 ppm; vegetable, fruiting, group 8 at 1.4 ppm; borage, seed at 0.45 ppm; castor oil plant, seed at 0.45 ppm; chinese tallowtree, seed at 0.45 ppm; crambe, seed at 0.45 ppm; cuphea, seed at 0.45 ppm; echium, seed at 0.45 ppm; euphorbia, seed at 0.45 ppm; evening primrose, seed at 0.45 ppm; flax seed at 0.45 ppm; gold of pleasure, seed at 0.45 ppm; hare’s ear mustard, seed at 0.45 ppm, jojoba, seed at 0.45 ppm; lesquerella, seed at 0.45 ppm, lunaria, seed at 0.45 ppm; meadowfoam, seed at 0.45 ppm; milkweed, seed at 0.45 ppm; mustard, seed at 0.45 ppm; niger seed, seed at 0.45 ppm; oil radish, seed at 0.45 ppm; poppy, seed at 0.45 ppm; rapeseed, seed at 0.45 ppm; rose hip, seed at 0.45 ppm; safflower, seed at 0.45 ppm; sesame, seed at 0.45 ppm; stokes aster, seed at 0.45 ppm; sunflower, seed at 0.45 ppm; sweet rocket, seed at 0.45 ppm; tallowwood, seed at 0.45 ppm; tea oil plant, seed at 0.45 ppm; and ternonia, seed at 0.45 ppm. That document referenced a summary of the petition prepared on behalf of IR-4 by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Additionally, in the **Federal Register** of August 22, 2012 (77 FR 50661) (FRL-9358-9), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8038) by BASF

Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC, 27709–3528.

The petition requested that 40 CFR 180.582 be amended by establishing tolerances for residues of the fungicide pyraclostrobin, carbamic acid, expressed as the parent compound, in or on sugarcane, cane at 0.2 ppm. No tolerances were proposed for the processed commodities refined sugar and molasses, as no concentration of pyraclostrobin residues are expected in these commodities. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance level in or on endive, belgium. Further, the petitioner later requested to amend low growing berry subgroup 13–07G to exclude cranberry. The reasons for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a

reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyraclostrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyraclostrobin follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

There are no concerns for reproductive susceptibility, neurotoxicity, mutagenicity, genotoxicity, or immunotoxicity. The most consistently observed effects resulting from pyraclostrobin exposure across species, genders, and treatment durations were diarrhea and decreased body weight, body weight gain, and food consumption. Pyraclostrobin also causes intestinal disturbances, as indicated by increased incidence of diarrhea or duodenum mucosal thickening. These intestinal effects appeared to be related to the irritating action on the mucus membranes as demonstrated by irritation seen in the primary eye irritation study. In the rat acute and subchronic neurotoxicity studies, neuropathology and behavior changes were not observed.

In the rat developmental toxicity study, developmental toxicity including an increased incidence of dilated renal pelvis and cervical ribs occurred at a dose greater than the dose causing maternal toxicity (including decreased body weights and body weight gains and reduced food consumption and reduced food efficiency). The rabbit developmental toxicity study indicates qualitative evidence of increased developmental susceptibility based on increased resorptions per litter, increased post-implantation loss and dams with total resorptions, in the presence of maternal toxicity (reduced body weight gain, food consumption, and food efficiency). In a dose range-finding one-generation reproduction study, systemic toxicity was manifested as decreased body weight and body weight gain in both the parents and offspring. The effects occurred at the same dose levels for both parental and the offspring, but the decrease in pup weight was more than that in the parental animals. However, the body weight effect was not found in the guideline 2-generation reproduction study in either parental or offspring animals at similar dose level. No reproductive toxicity was seen.

Pyraclostrobin has been classified as not likely to be carcinogenic to humans based on the lack of treated related increase in tumor incidence in adequately conducted carcinogenicity studies in rats and mice. Pyraclostrobin did not cause mutagenicity or genotoxicity in the *in vivo* and *in vitro* assays, nor did it cause immunotoxicity in T-cell dependent antibody response assays in mice with preliminary review.

Specific information on the studies received and the nature of the adverse effects caused by pyraclostrobin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document: “Pyraclostrobin – Human Health Risk



Assessment for a Section 3 Registration of New Uses on Sugarcane, Globe Artichoke, Belgium Endive, Persimmon, Greenhouse Grown Tomato Transplants for Home Consumer Market, and Residential Ornamentals, Landscape Gardens, Fruit Trees, and Nut Trees; Plus Crop Group Expansions/Revisions for Bulb Vegetable Group 3-07, Fruiting Vegetable Group 8-10, Citrus Fruit Group 10-10, Pome Fruit Group 11-10, Berry Subgroups 13-07A, B, F, and G, and Oilseed Group 20” at pages 43-49 in docket ID number EPA-HQ-OPP-2012-0549.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete

description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for pyraclostrobin used for human risk assessment is shown in Table 1. of this unit.

**Table 1.--Summary of Toxicological Doses and Endpoints for Pyraclostrobin for Use in Human Health Risk Assessment**

<b>Exposure/Scenario</b>	<b>Point of Departure and Uncertainty/Safety Factors</b>	<b>RfD, PAD, LOC for Risk Assessment</b>	<b>Study and Toxicological Effects</b>
Acute dietary (Females 13-49 years of age)	NOAEL = 5.0 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Acute RfD = 0.05 mg/kg/day  aPAD = 0.05 mg/kg/day	Developmental toxicity – rabbit LOAEL = 10.0 mg/kg/day based on developmental toxicity findings of increased resorptions.
Acute dietary (General population including infants and children)	NOAEL = 300 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Acute RfD = 3.0 mg/kg/day  aPAD = 3.0 mg/kg/day	Acute neurotoxicity – rat LOAEL = 1000 mg/kg/day based on decreased body weight gain in males.
Chronic dietary (All populations)	NOAEL = 3.4 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Chronic RfD = 0.034 mg/kg/day  cPAD = 0.034 mg/kg/day	Carcinogenicity – rat LOAEL = 9.2 mg/kg/day based on decreased body weight/body weight gain, kidney tubular casts and atrophy in both sexes; increased incidence of liver necrosis and erosion/ulceration of the glandular-stomach and fore-stomach in males.
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months)	NOAEL = 5.8 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Subchronic toxicity – dog LOAEL = 12.9 mg/kg/day based on increased incidence of diarrhea, clinical chemistry changes, duodenum mucosal hypertrophy, and decreased body weight and food intake/efficiency.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Oral study NOAEL = 5.0 mg/kg/day (dermal absorption rate = 14%)	LOC for MOE = 100	Developmental toxicity – rabbit LOAEL = 10.0 mg/kg/day based on developmental

	$UF_A = 10 \times$ $UF_H = 10 \times$ FQPA SF = 1x		toxicity findings of increased resorptions and maternal toxicity based on decreased body weight gain and decreased food intake/efficiency.
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Inhalation study NOAEL = 0.23 mg/kg/day $UF_A = 10 \times$ $UF_H = 10 \times$ FQPA SF = 1x	LOC for MOE = 100	Inhalation toxicity – rat LOAEL = 6.9 mg/kg/day (air concentration = 0.03 mg/L) based on duodenum mucosal hyperplasia and respiratory system findings including alveolar histiocytosis and olfactory atrophy/necrosis in nasal tissue.
Cancer (Oral, dermal, inhalation)	Classification: “not likely to be carcinogenic to humans” based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor.  $UF_A$  = extrapolation from animal to human (interspecies).  $UF_H$  = potential variation in sensitivity among members of the human population (intraspecies).

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyraclostrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing pyraclostrobin tolerances in 40 CFR 180.582. EPA assessed dietary exposures from pyraclostrobin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for pyraclostrobin.

In estimating acute dietary exposure, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16,

which uses food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) from 2003 through 2008. As to residue levels in food, EPA used tolerance-level residues or highest field trial residues and empirical or default processing factors. Experimentally-derived processing factors were used for fruit juices, tomato, sugarcane, and wheat commodities. For all other processed commodities, DEEM default processing factors were assumed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA included tolerance-level or average field trial residues, average percent crop treated (PCT) estimates when available, and empirical processing factors. Experimentally-derived processing factors were used for fruit juices, tomato, sugar cane, and wheat commodities. For all other processed commodities, DEEM default processing factors were assumed.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that pyraclostrobin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Percent crop treated (PCT) information.* Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The following average PCT estimates were used in the chronic dietary risk assessments for the crops that are currently registered for pyraclostrobin: almonds 40%; apples 15%; apricots 25%; barley 10%; green beans 5%; blueberries 45%; broccoli 5%; cabbage 10%; caneberries 50%; cantaloupes 15%; carrots 35%; cauliflower 2.5%; celery 2.5%; cherries 50%; corn 10%; cotton 2.5%; cucumber 5%; dry beans/peas 10%; garlic 15%; grapefruit 25%; grapes 30%; hazelnuts (filberts) 15%; lemons 2.5%; lettuce 5%; nectarines 10%; onions 20%; oranges 5%; peaches 20%; peanuts 25%; pears 15%; green peas 5%; pecans 2.5%; peppers 10%; pistachios 30%; plums/prunes 5%; potatoes 15%; pumpkins 20%; soybeans 5%; spinach 5%; squash 15%; strawberries 65%; sugar beets 45%; sweet corn 5%; tangelos 15%; tangerines 10%; tomatoes 25%; walnuts 1%; watermelons 30%; wheat 5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis.

The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which pyraclostrobin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyraclostrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyraclostrobin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of pyraclostrobin for acute exposures are estimated to be 35.6 parts per billion (ppb) for surface water and 0.06 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 2.3 ppb for surface water and 0.02 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 35.6 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 2.3 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Pyraclostrobin is currently registered for the following uses and additional proposed uses that could result in residential handler and postapplication exposures: Treated gardens, fruit or nut trees, tomato transplants, and turf. EPA assessed residential exposure using

the following assumptions: Short-term adult handler exposures via the dermal and inhalation routes resulting from application of pyraclostrobin to gardens, trees, and turf. Short-term dermal postapplication exposures were assessed for adults, youth 11 to 16 years old, and children 6 to 11 years old. Short-term dermal and incidental oral exposures were assessed for children 1 to < 2 years old. Based on the registered uses of pyraclostrobin on residential and golf course turf, intermediate-term postapplication exposures are possible. However, since the short- and intermediate-term endpoints and PODs for dermal and oral routes are the same, the short-term exposure and risk estimates are considered to be protective of potential intermediate-term exposure and risk.

For the aggregate assessment, inhalation and dermal exposures were not aggregated together because the toxicity effect from the inhalation route of exposure was different than the effect from the dermal route of exposure. The scenarios with the highest residential exposures that were used in the short-term aggregate assessment for pyraclostrobin are as follows:

- Adult short-term aggregate assessment- Residential inhalation exposure from application pyraclostrobin to turf via manually pressurized hand wand or backpack sprayer; residential dermal postapplication exposure via activities on treated turf.
- Youth (11-16 years old) short-term aggregate assessment- Residential dermal exposure from postapplication golfing on treated turf.
- Children (6-11 years old) short-term aggregate assessment- Residential dermal exposures from postapplication activities in treated gardens.



- Children (1 < 2 years old) short-term aggregate assessment- Residential dermal and hand-to-mouth exposures from postapplication exposure to treated turf.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

#### 4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found pyraclostrobin to share a common mechanism of toxicity with any other substances, and pyraclostrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyraclostrobin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is

commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence that pyraclostrobin results in increased susceptibility in rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. Although there is qualitative evidence of increased susceptibility in the prenatal development study in rabbits, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of pyraclostrobin. The degree of concern for prenatal and/or postnatal toxicity is low.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for pyraclostrobin is complete.
- ii. There is no indication that pyraclostrobin is a neurotoxic chemical. Effects seen in the acute and subchronic neurotoxicity studies in rats are considered to reflect perturbations in mitochondrial respiration leading to effects on energy production rather than signs of neurotoxicity; therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity
- iii. There is no evidence that pyraclostrobin results in increased susceptibility in rats in the prenatal developmental study or in young rats in the 2-generation reproduction study. The prenatal rabbit developmental toxicity study showed qualitative evidence of increased susceptibility to prenatal rabbits; however, this study was chosen for endpoint

selection for the acute dietary (females 13-49) and short-term dermal exposure scenarios. This study has a clearly defined NOAEL of 5.0 mg/kg/day. EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of pyraclostrobin. The degree of concern for prenatal and/or postnatal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary exposure assessments were performed assuming 100 PCT and tolerance-level or highest field trial residues. The chronic dietary exposure assessments were performed using average PCT estimates, when available, and tolerance-level or highest field trial residues. These data are reliable and are not expected to underestimate risks to adults or children. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyraclostrobin in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pyraclostrobin.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyraclostrobin will occupy 87% of the aPAD for females 13-49 years old; and 2.8% for children 1-2 years old, the population group receiving the greatest exposure for the general U.S. population, including infants and children.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyraclostrobin from food and water will utilize 27% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pyraclostrobin is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pyraclostrobin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to pyraclostrobin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 120 for children 1-2 years old, 360 for children 6-11 years old, 1,500 for youth 11-16 years old, 760 for adult handlers, and 230 for adults from

postapplication exposures. Because EPA's level of concern for pyraclostrobin is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pyraclostrobin is currently registered for uses that could result in intermediate-term residential exposure; however, since the short- and intermediate-term endpoints and PODs for dermal and oral routes are the same, the short-term exposure and risk estimates are considered to be protective of potential intermediate-term exposure and risk and an intermediate-term aggregate assessment was not performed.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, pyraclostrobin is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to pyraclostrobin residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Two adequate methods are available to enforce the tolerance expression for residues of pyraclostrobin and the metabolite BF 500-3 in or on plant commodities: A liquid chromatography with tandem mass spectrometry (LC/MS/MS) method, BASF Method D9908; and a high-performance LC with ultraviolet detection (HPLC/UV) method, Method D9904. The methods may be found in the *Pesticide Analytical Manual*,

Volume I.

*B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for pyraclostrobin in or on sugarcane, endive, belgium, and persimmon. A Codex MRL has been established for pyraclostrobin in or on globe artichoke at 2.0 ppm. EPA has determined that the U.S. tolerance should be set at 3.0 ppm. The field trials comprising the data set used by Codex are from Europe, and these trials were conducted under an application rate and preharvest interval different from that on the U.S. trials. The U.S. tolerance is based on application of the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures to the validated field trial data, which shows that the U.S. tolerance for globe artichoke must be at 3.0 ppm to avoid violations for crops treated in accordance with the EPA approved label. These different tolerance levels may be due, in part, to the different residue definitions for pyraclostrobin for the U.S. tolerances and the Codex MRLs.

Codex established MRLs for residues of pyraclostrobin only, and in the U.S. tolerances, are currently established for parent and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl] phenylcarbamate). Currently, pyraclostrobin has over 100 tolerances for multiple commodities and crop groups. When this chemical goes through registration review the U.S. EPA will determine if it is possible to change the existing residue definition to align with Codex which would potentially allow for harmonization of MRL and tolerance levels. However, given the number of existing tolerances it is not appropriate to consider such a change for this petition only.

Therefore, because the residue definitions are currently different and pyraclostrobin field trials in the U.S. show higher residue levels than Codex MRL levels, it is not possible to harmonize the U.S. tolerance for globe artichoke with the Codex MRL. Additionally, the following U.S. crop group tolerances established in this action could not be harmonized because of the difference in residue definitions between U.S. tolerances for

pyraclostrobin and Codex MRLs. The crop group tolerances which could not be harmonized with Codex MRLs for commodities in these crop group tolerances include:

The bulb vegetable group 3-07; the fruiting vegetables group 8-10; the pome fruit group 11-10; the caneberry subgroup 13-07A; the bushberry subgroup 13-07B; the small fruit vine climbing subgroup 13-07F; and the low growing berry subgroup 13-07G. The

Codex has established an MRL for the Codex equivalent of the U.S. citrus fruit group 10-10 and for the oilseed group 20, but although the numerical levels for the U.S. and Codex crop groups are the same, the numerical values refer to different residues.

### *C. Revisions to Petitioned-For Tolerances*

Based on the data submitted with the petition, EPA is revising the proposed tolerance in or on endive, belgium from 3.0 ppm to 4.0 ppm. The Agency revised this tolerance level based on analysis of the residue field trial data using the OECD tolerance calculation procedures. EPA is additionally removing the time-limited tolerance in or on sugarcane, cane at 0.02 ppm as it will be superseded by the permanent tolerance at 0.2 ppm. Finally, EPA is removing the time-limited tolerance in or on sugarcane, molasses at 0.4 ppm, as the Agency has determined that no concentration of pyraclostrobin residues are expected in these commodities and the tolerance is therefore not necessary. The information regarding sugarcane, molasses was included in the August 22, 2012 (77 FR 50661) notice of filing for PP number 2F8038.

### **V. Conclusion**

Therefore, tolerances are established for residues of pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl *N*-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl carbamate), calculated as the stoichiometric equivalent of pyraclostrobin in or on artichoke, globe at 3.0 ppm; endive, belgium at 4.0 ppm; persimmon at 3.0 ppm; sugarcane, cane at 0.20 ppm; vegetable, bulb, group 3-07 at 0.9 ppm; vegetable, fruiting, group 8-10 at 1.4 ppm; fruit, citrus, group 10-10 at 2.0 ppm; fruit, pome, group 11-10 at 1.5 ppm; oilseed group 20 at 0.45 ppm; caneberry subgroup 13-07A at 4.0 ppm; bushberry subgroup 13-07B at 4.0 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm; and berry, low growing, subgroup 13-07G, except cranberry at 1.2 ppm. This regulation additionally removes established



tolerances in or on vegetable, bulb, group 3; vegetable, fruiting, group 8; fruit, citrus, group 10; fruit, pome, group 11; cotton, undelinted seed; borage, seed; castor oil plant, seed; Chinese tallowtree, seed; crambe, seed; cuphea, seed; echium, seed; euphorbia, seed; evening primrose, seed; flax, seed; gold of pleasure, seed; hare's ear mustard, seed; jojoba, seed; lesquerella, seed; lunaria, seed; meadowfoam, seed; milkweed, seed; mustard, seed; niger seed, seed; oil radish, seed; poppy, seed; rapeseed, seed; rose hip, seed; safflower, seed; sesame, seed; stokes aster, seed; sunflower, seed; sweet rocket, seed; tallowwood, seed; tea oil plant, seed; vernonia, seed; berry, group 13; grape; and strawberry. This regulation finally removes the time-limited tolerances in or on sugarcane, cane and sugarcane, molasses.

## **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under

Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

## VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 14, 2013.

Lois Rossi,

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.582:

a. Revise the table in paragraph (a)(1).

b. Remove the commodities “Sugarcane, cane” and “Sugarcane, molasses” in the table in paragraph (b).

c. Revise the table in paragraph (b).

The revisions read as follows:

**§ 180.582 Pyraclostrobin; tolerances for residues.**

(a) *General.* (1) \* \* \*

<b>Commodity</b>	<b>Parts per million</b>
Alfalfa, forage	10
Alfalfa, hay	30
Almond, hulls	7.0
Apple, wet pomace	8.0
Artichoke, globe	3.0
Avocado	0.6
Banana	0.04
Barley, grain	1.4
Barley, hay	25
Barley, straw	6.0
Bean, succulent shelled	0.5
Beet, sugar, dried pulp	1.0
Beet, sugar, roots	0.2
Beet, sugar, tops	8.0
Berry, low growing, subgroup 13-07G, except cranberry	1.2
Brassica, head and stem, subgroup 5A	5.0
Brassica, leafy greens, subgroup 5B	16.0

Bushberry subgroup 13-07B	4.0
Caneberry subgroup 13-07A	4.0
Canistel	0.6
Citrus, dried pulp	12.5
Citrus, oil	9.0
Coffee, green bean	0.3 <sup>1</sup>
Corn, field, forage	5.0
Corn, field, grain	0.1
Corn, field, refined oil	0.2
Corn, field, stover	17.0
Corn, pop, grain	0.1
Corn, pop, stover	17.0
Corn, sweet, forage	5.0
Corn, sweet, kernel plus cob with husks removed	0.04
Corn, sweet, stover	23.0
Cotton, gin byproducts	30
Endive, belgium	4.0
Fruit, citrus, group 10-10	2.0
Fruit, pome, group 11-10	1.5
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	2.0
Fruit, stone, group 12	2.5
Grain, aspirated fractions	2.5
Grape, raisin	7.0
Grass, forage	10
Grass, hay	4.5
Grass, seed screenings	27
Grass, straw	14
Hop, dried cones	23.0
Mango	0.6
Nut, tree, group 14	0.04
Oat, grain	1.2
Oat, hay	18
Oat, straw	15
Oilseed group 20	0.45
Papaya	0.6
Pea, succulent	0.2
Pea and bean, dried shelled, except soybean, subgroup 6C	0.5
Peanut	0.05
Peanut, refined oil	0.1
Peppermint, tops	8.0
Persimmon	3.0
Pistachio	0.7

Radish, tops	16
Rye, grain	0.04
Rye, straw	0.5
Sapodilla	0.6
Sapote, black	0.6
Sapote, mamey	0.6
Sorghum, grain, forage	5.0
Sorghum, grain, grain	0.60
Sorghum, grain, stover	0.80
Soybean, forage	11
Soybean, hay	14
Soybean, hulls	0.06
Soybean, seed	0.04
Spearmint, tops	8.0
Star apple	0.6
Sugarcane, cane	0.20
Vegetable, bulb, group 3-07	0.9
Vegetable, cucurbit, group 9	0.5
Vegetable, foliage of legume, except soybean, subgroup 7A	25.0
Vegetable, fruiting, group 8-10	1.4
Vegetable, leafy, except brassica, group 4	29.0
Vegetable, leaves of root and tuber, group 2, except sugar beet	16.0
Vegetable, legume, edible podded, subgroup 6A	0.5
Vegetable, root, except sugar beet, subgroup 1B	0.4
Vegetable, tuberous and corm, subgroup 1C	0.04
Vegetables, foliage of legume, group 7	25
Wheat, grain	0.02
Wheat, hay	6.0
Wheat, straw	8.5

\* \* \* \*

(b) *Section 18 emergency exemptions.* \* \* \*

Commodity	Parts per million	Expiration/revocation date
Endive, belgium	11.0	12/31/13

\* \* \* \* \*

[FR Doc. 2013-20921 Filed 08/27/2013 at 8:45 am; Publication Date: 08/28/2013]